K111652
p1/3

Exhibit#1

JUL 13 2011

## 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

**1. Submitter's Identification:**

Microlife Intellectual Property GmbH, Switzerland
Espenstrasse 139
9443 Widnau / Switzerland

Date Summary Prepared: June 1, 2011

Contact: Mr. Gerhard Frick
Vice President of Technical and Service
Microlife Intellectual Property GmbH, Switzerland
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**2. Name of the Device:**

Automatic Talking Blood Pressure Monitor, Model BP3AP1-3E (BP A130)

Regulation Number: 21 CFR Part 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: II
Product Code: DXN

**3. Information for the 510(k) Cleared Device (Predicate Device):**

a. Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MC1-PC, K061471, Microlife Intellectual Property GmbH.

b. Reizen Talking Blood Pressure Monitor, Model SF860T, K041778, Maxi Aids, Inc.

**4. Device Description:**

Microlife Automatic Talking Blood Pressure Monitor, Model BP3AP1-3E (BP A130) is designed to measure systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses a capacitor pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well - known technique in the market called the "oscillometric method".

The device has Irregular Heartbeat Detection (IHD) function. It detects the appearance of irregular heartbeat during measurement and the irregular heart beat

symbol "⩘" is displayed on the LCD screen if any irregular heart beat signal has been detected. In addition, the device has talking function, traffic light and medication alarm function.

5. **Intended Use:**

The Automatic Talking Blood Pressure Monitor, Model BP3AP1-3E (BP A130) is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm.

The device detects the appearance of irregular heartbeat during measurement and gives a warning signal with the reading once the irregular heartbeat is detected.

6. **Comparison to the 510(k) Cleared Devices (Predicate Devices):**

The subject BP3AP1-3E (BP A130) and the predicate device model BP3MC1-PC, use the same oscillometric method with the same software algorithm to determine the systolic and diastolic blood pressure and pulse rate. Upper arm cuff is inflated automatically by pump, the deflation rate is controlled by factory set exhaust valve and the deflation pressures are transferred via tubing to a sensor in these two units.

The differences between the two models are the talking function, MAM, PC-link function, backlight, cuff bladder material and cuff bladder size but the differences do not affect the accuracy and normal use of this device because they use the same fundamental scientific technology based on the internal clinical test comparing different cuff bladder material and the clinical test on three cuffs with different bladder size.

The talking function is same with what is used in the predicate device, Model SF860T, with 510(k) cleared number K041778.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing information demonstrating safety and effectiveness of the Microlife Automatic Talking Blood Pressure Monitor, Model BP3AP1-3E (BP A130) in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance requirements.

The following testing was conducted:

a. Reliability Test - Storage test
b. Reliability Test - Operating test
c. Reliability Test - Vibration test
d. Reliability Test - Drop test
e. Reliability Test - Life test
f. EMC Test

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was

our conclusion that Microlife Automatic Talking Blood Pressure Monitor, Model BP3AP1-3E (BP A130) tested met all relevant requirements of the aforementioned tests.

**8. Discussion of Clinical Tests Performed:**

The subject modified device Model BP3AP1-3E (BP A130) is from the technical point of view, identical to the blood pressure monitor Model BP3MC1-PC. The internal clinical test comparing different cuff bladder materials demonstrates that the clinical accuracy in terms of blood pressure detection and normal use of this device is not affected by change of the bladder material from PVC to TPU. The clinical tests on three cuffs with different bladder size demonstrate that the clinical accuracy in terms of blood pressure detection and normal use of this device is not affected by change of the bladder size. The other differences (talking function, MAM, PC-link function, backlight) have no impact on the clinical accuracy in terms of blood pressure detection. Therefore repeated clinical test in accordance with the standard ANSI/AAMI SP10 is not necessary.

**9. Software information:**

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

**10. Conclusions:**

We have demonstrated that there are no significant differences between the Microlife Automatic Talking Blood Pressure Monitor, Model BP3AP1-3E (BP A130) and the predicate devices, Model BP3MC1-PC and Model SF860T, in terms of safety and effectiveness based on electrical, mechanical and environmental test results per the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", and the ANSI/AAMI Voluntary Standard, SP10: 2008.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Microlife Intellectual Property GmbH, Switzerland
c/o Ms. Susan D. Goldstein-Falk
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

JUL 13 2011

Re: K111652
Trade/Device Name: Microlife Automatic Talking Blood Pressure Monitor, BP3AP1-3E (BP A130)
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: June 10, 2011
Received: June 13, 2011

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

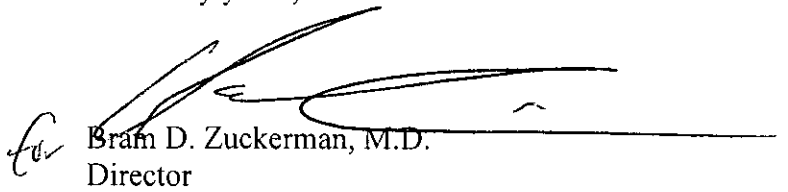
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111652

Exhibit B

# Indications for Use

**510(k) Number (if known):** _____

**Device Name:** Microlife Automatic Talking Blood Pressure Monitor, Model BP3AP1-3E (BP A130)

**Indications For Use:**

The Automatic Talking Blood Pressure Monitor, Model BP3AP1-3E (BP A130) is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm.

The device detects the appearance of irregular heartbeat during measurement and gives a warning signal with the reading once the irregular heartbeat is detected.

**Prescription Use** _____ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** __X____ (21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111652